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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,151	10/30/2001	Jeffrey R. Balser	1242/49/2	8248

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/000,151	BALSER ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-99* is/are pending in the application.

4a) Of the above claim(s) *4-6 and 20-99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 7-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-99* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendments of 19 July 2004 and 09 April 2004 have been entered in full. Claims 1, 7-11, and 15-17 are amended.

This application contains claims 4-6 and 20-99 drawn to an invention nonelected without traverse in the communication of 30 July 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3 and 7-19 are under consideration in the instant application.

Sequence Compliance

The Applicant's response to the Notice to Comply with Sequence Listing Requirements under 37 CFR §1.821 (19 July 2004 and 09 April 2004) has been considered and is found persuasive. Therefore, the requirements set forth in the Notice to Comply (10 November 2003) are *withdrawn*.

Withdrawn Objections and/or Rejections

1. The objections to the specification at pg 3 of the previous Office Action (10 November 2003) are *withdrawn* in view of the amended specification (09 April 2004).

2. The objection to claim 8 at pg 3 of the previous Office Action (10 November 2003) is *withdrawn* in view of the amended claim (09 April 2004).

3. The rejections of claims 1-3 and 7-19 under 35 U.S.C. § 112, second paragraph as set forth at pg 9 of the previous Office Action (10 November 2003) are *withdrawn* in view of the amended claims (09 April 2004). Please see 35 U.S.C. § 112, second paragraph, below.

Claim Rejections – 35 U.S.C. § 112, first paragraph

4. Claims 1-3 and 7-19 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of identifying a compound that modulates the transmission of potassium ions through a human ether-a-go-go-related gene (HERG) potassium channel, comprising: (a) culturing a cell comprising a HERG potassium channel of SEQ ID NO: 3 and a K+ channel regulator 1 (KCR1) polypeptide encoded by the nucleic acid sequence of SEQ ID NO: 1; (b) contacting the cell with a test compound; (c) measuring potassium transmission through the HERG channel in the presence of the test compound; and (d) comparing the potassium transmission through the HERG channel in the presence of the test compound to the potassium transmission through the HERG channel in the absence of the test compound, wherein a difference between potassium transmission by the HERG channel in the absence of the test compound and potassium transmission by the HERG channel in the presence of the test compound indicates modulation of potassium transmission by the HERG channel, *does not reasonably* provide enablement for a method of identifying a compound that modulates a potassium transmission by a potassium channel comprising, (a) providing a structure comprising a potassium channel, wherein the structure comprises a potassium channel polypeptide and a KCR1 polypeptide; (b) contacting the test compound with the structure; (c) determining potassium transmission by the potassium channel polypeptide in the presence of the test compound; (d) comparing the potassium transmission by the potassium channel in the

presence of the test compound to potassium transmission by the potassium channel in an absence of test compound, wherein a difference between the potassium transmission by the potassium channel in the absence of the test compound and potassium transmission of the potassium channel in the presence of test compound indicates modulation of potassium transmission by the potassium channel. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pg 3-6 of the previous Office Action (10 November 2003).

The claims also recite that the structure is a cell and that the cell is isolated from a subject. The claims recite that the potassium channel is HERG, which comprises the polypeptide sequence set forth in SEQ ID NO: 3. The claims recite that the KCR1 polypeptide is encoded by the nucleic acid comprising SEQ ID NO: 1. The claims also recite that the determining comprises employing a patch clamp apparatus and that the biological activity of a structure comprising a potassium channel polypeptide and a KCR1 polypeptide in the presence of a test compound is determined in the presence of an MiRP1 polypeptide, which is encoded by a nucleic acid comprising SEQ ID NO: 4.

Applicant's arguments (09 April 2004), as they pertain to the rejections have been fully considered but are not deemed to be persuasive.

(i) Applicant asserts that the burden rests upon the Patent Office to establish a *prima facie* case of a failure to comply with 35 U.S.C. § 112, first paragraph, with respect to the invention described and claimed in the patent application. Applicant argues that no specific scientific or other factual basis has been presented in the Official Office Action. Applicant contends that the

Patent Office has cited no patents, no journal articles, and no other references in support of its position, other than to assert that potassium channels make up a large class of proteins. Applicant argues that the Patent Office has offered only a series of conclusory statements. Applicant also states that 35 U.S.C. § 112, first paragraph, requires no more than a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims. It is noted that Applicant cites *In re Marzocci* (58 C.C.P.A. 1069, 439 F.2d 220, 169 USPQ 367 (C.C.P.A. 1971)).

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant has not specifically identified any assertions made by the Examiner that are being challenged. A *prima facie* case of lack of enablement under 35 U.S.C. § 112, first paragraph was made in the previous Office Action (10 November 2003). Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to screen all possible potassium channels with all possible compounds for potassium transmission, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the structural and functional diversity of potassium channels, and the breadth of the claims which fail to recite any limitations as to the potassium channel to be examined in the assay, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. It is also noted that although patents, journal articles, and other references are not required to established a *prima facie* case of lack of enablement, the Examiner cited two references in the previous Office Action to establish the state of the art at the time the invention was made (see pg 6 of the previous Office Action, 10

November 2003; Skolnick et al. and Lehmann-Horn et al.). Furthermore, Applicant's argument fails to address the merits of the rejection and does not provide fact or evidence to the contrary.

(ii) Applicant indicates that while it might require considerable experimentation to practice the instant invention, the quantity of experimentation to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. It is noted that Applicant cites *In re Colianni* 195 USPQ 150, 153 (C.C.P.A. 1977), *In re Wands*, 8 USPQ 2d at 1404, and *U.S. Telectonics, Inc.*, 8 USPQ 2d 1217, 1223 (Fed. Cir. 1988), cert. denied, 490 US 1046 (1989).

Applicant's arguments have been fully considered but are not found to be persuasive. According to MPEP § 2164.06, "the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed. For example, if a very difficult and time consuming assay is needed to identify a compound within the scope of the claim, then this great quantity of experimentation should be considered in the overall analysis". Additionally, as was found in Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity. See also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991). The specification of the instant application does not teach identifying compounds that modulate potassium transmission of all possible potassium channels.

The specification does not teach screening for substances capable of modulation of potassium transmission using any potassium channels other than HERG (SEQ ID NO: 3) in conjunction with a human KCR1 polypeptide (encoded by the nucleic acid sequence of SEQ ID NO: 1). As discussed in the previous Office Action (10 November 2003), undue experimentation would be required of the skilled artisan to screen all possible potassium channels and their derivatives with all possible compounds for potassium transmission. Skolnick et al. (Trends in Biotech 18:34-39) states that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating the specific details of protein function (see Box 2, pg 36). Relevant literature reports that that potassium channels constitute the most diverse class of ion channels with respect to kinetic properties, regulation, pharmacology, and structure (pg 1329, col 2; Tables 3-4; Lehmann-Horn et al. Physiol Rev 79 (4): 1317-1372, 1999). Additionally, over 13 subfamilies have been in humans in both excitable and non-excitable cell types (Lehmann-Horn et al., pg 1329, col 2; pg 1330, col 1). Lehmann-Horn et al. discuss mutations in *potassium* channels that cause a wide spectrum of hereditary and somatic conditions and diseases. For example, the ***single*** mutation of a valine residue to a phenylalanine residue at position 174 in the human Kv1.1 gene results in episodic ataxia type 1 (see Table 12; also pg 1333, ¶ 2; pg 1346-1349; pg 1350-1351). Additionally, even point mutations in the HERG gene, cause long Q-T syndrome 2, wherein the mutations suppress repolarization of the myocardial action potential, lengthening the Q-T interval by either loss of function or haploinsufficiency (Lehmann-Horn et al., pg 1348, col 2; Table 10). One skilled in the art would not be able to predict that all potassium channels have the same function, if a function at all. Therefore, since the specification provides no guidance regarding what type of potassium

channels should be screened for the desired activity, the skilled artisan must resort to trial and error experimentation to determine which potassium channels and their derivatives might yield one with the desired activity. Such trial and error experimentation is considered undue.

Furthermore, the fact pattern of the instant application is not inconsistent with *In re Colianni* or *In re Wands*. However, as discussed above, the specification of the instant application does not teach identifying compounds that modulate potassium transmission of all possible potassium channels. The skilled artisan must resort to trial and error experimentation to generate the infinite number of potassium channels and their derivatives, as recited in the claims, and to screen them for a desired activity. Such trial and error is considered undue. The Examiner is unable to fully examine the fact pattern or comment on Applicant's citation of *U.S. Telectonics, Inc* because the Examiner cannot readily determine which page Applicant is referring to. It appears that the fact patterns of *U.S. Telectonics, Inc* (which is drawn to patent infringement) and that of the instant rejection are significantly different, and the court decisions are not binding with regard to the instant rejections.

(iii) Applicant asserts that working examples are not required under 35 U.S.C. § 112, first paragraph, to comply with the enablement standard. Applicant submits that the specification supplies amply working examples for a structure comprising a potassium channel, wherein the potassium channel comprises a potassium channel polypeptide and KCR1, contacting the potassium channel with a test compound, and determining potassium transmission by the potassium channel in the presence or absence of the test compound. Applicant contends that since the nature of the specific potassium channel polypeptide and the test compound employed

do not impact the assay, the disclosed techniques can be used to test any test compound on any structure comprising a KCR1 polypeptide and any other potassium channel polypeptide. Applicant argues that applicable assays are provided, namely the patch clamp or voltage clamp protocols that are used to measure potassium currents.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, undue experimentation would be required of the skilled artisan to generate and screen all possible potassium channels for potassium transmission activity. The specification's general discussion of making and screening for variants constitutes (the bottom of pg 45 through pg 53) an invitation to experiment by trial and error. Such trial and error experimentation is considered undue. Although Applicant submits that the nucleic acid/protein synthesis and screening processes are routine, Applicant has provided little or no guidance to enable one or ordinary skill in the art to determine, without undue experimentation, the positions any potassium channel protein and DNA sequences which are tolerant to change and the nature and extent of changes that can be made in these positions. A specification may be enabling even though some experimentation is necessary, but the amount of experimentation, however, must not be unduly extensive (MPEP § 2164.06). Lehmann-Horn et al. teach that over 13 subfamilies of potassium channel have been described, including voltage-gated channels and voltage-insensitive channels (pg 1329-1332). Lehmann-Horn et al. discuss mutations in *potassium* channels that cause a wide spectrum of hereditary and somatic conditions and diseases. For example, the ***single*** mutation of a valine residue to a phenylalanine residue at position 174 in the human Kv1.1 gene results in episodic ataxia type 1 (see Table 12; also pg 1333, ¶ 2; pg 1346-1349; pg 1350-1351). Additionally, even point mutations in the HERG gene, for instance, cause

long Q-T syndrome 2, wherein the mutations suppress repolarization of the myocardial action potential, lengthening the Q-T interval by either loss of function or haploinsufficiency (Lehmann-Horn et al., pg 1348, col 2; Table 10). One skilled in the art would not be able to predict that all potassium channels have the same function, if a function at all. Thus, a specific potassium channel polypeptide and its function do impact the claimed assay.

Although Applicant submits that the specification supplies amply working examples for a structure comprising a potassium channel and that applicable assays are provided, namely the patch clamp or voltage clamp protocols, Applicant has not indicated where in the specification support can be found for such assertions.

(iv) Applicant argues that while the specification teaches that cells were transfected with HERG, KCR1, and MiRP1, any other potassium channel polypeptide could be used in place of HERG. Applicant also indicates that the amount of experimentation necessary to determine whether a test compound modulated the activity of a potassium channel comprising this other potassium channel polypeptide would be no greater than that required to test the HERG channel exemplified in the working examples. Applicant asserts that the claims do not require that all possible channels or compounds be screened, but rather, recite that a structure comprising a potassium channel polypeptide and KCR1 is provided and that the structure is contacted with the test compound. Applicant argues that while it might require considerable effort to screen all possible potassium channels with all possible compounds, this is not required by the claims. Applicant adds that assuming arguendo, the method of claim 1 did seek to identify all possible compounds, the experimentation required would not be undue.

Applicant's arguments have been fully considered but are not found to be persuasive. As discussed above, undue experimentation would be required of the skilled artisan to generate and screen all possible potassium channels for potassium transmission activity. The specification's general discussion of making and screening for variants constitutes (the bottom of pg 45 through pg 53) an invitation to experiment by trial and error. Applicant has not provided any evidence to indicate that any other potassium channels can be utilized in the claimed method. The state of the art indicates that mutations in *potassium* channels cause a wide spectrum of hereditary and somatic conditions and diseases. For example, the ***single*** mutation of a valine residue to a phenylalanine residue at position 174 in the human Kv1.1 gene results in episodic ataxia type 1 (see Table 12; also pg 1333, ¶ 2; pg 1346-1349; pg 1350-1351). Additionally, even point mutations in the HERG gene, cause long Q-T syndrome 2, wherein the mutations suppress repolarization of the myocardial action potential, lengthening the Q-T interval by either loss of function or haploinsufficiency (Lehmann-Horn et al., pg 1348, col 2; Table 10). One skilled in the art would not be able to predict that all potassium channels have the same function, if a function at all. Thus, a specific potassium channel polypeptide and its function do impact the claimed assay.

Applicant argues that while it might require considerable effort to screen all possible potassium channels with all possible compounds, this is not required by the claims. However, all possible potassium channels are encompassed in the recited method steps because the claims do not recite any limitations on the potassium channel. As mentioned above, according to MPEP § 2164.06, "the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed. For

example, if a very difficult and time consuming assay is needed to identify a compound within the scope of the claim, then this great quantity of experimentation should be considered in the overall analysis". Additionally, as was found in Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity. See also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991). . The specification of the instant application provides no guidance regarding what type of potassium channels should be screened for the desired activity, the skilled artisan must resort to trial and error experimentation to determine which potassium channels and their derivatives might yield one with the desired activity. Such trial and error experimentation is considered undue.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to screen all possible potassium channels with all possible compounds, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the structural and functional diversity of potassium channels, and the breadth of the claims which fail to recite any limitations as to the potassium channel to be examined in the assay, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

5. Claims 1-3 and 7-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is set for at pg 7-8 of the previous Office Action (10 November 2003).

Applicant's arguments (09 April 2004), as they pertain to the rejection have been fully considered but are not deemed to be persuasive.

(i) Applicant asserts that no specific scientific or other factual basis in support has been presented by the Office Action. Applicant submits that the Patent Office has offered only a series of conclusory statements, contending generally that the specification does not adequately describe to one of skill in the art the potassium channels of the encompassed methods. Applicant argues that 35 U.S.C. § 112, first paragraph, requires no more than a disclosure sufficient to convey to one of ordinary skill in the art that Applicant was in possession of the invention commensurate with the scope of the claims and that this requirement has been met. It is noted that Applicant cites the Written Description Guidelines, 66 Fed. Reg. at 1105.

Applicant's arguments have been fully considered but are not found to be persuasive. A *prima facie* case of lack of written description under 35 U.S.C. § 112, first paragraph was made in the previous Office Action (10 November 2003). The Examiner provided reasons why one skilled in the art would not have recognized that the inventors were not in possession of the invention as claimed in view of the disclosure of the application as filed. Specifically, the specification only teaches that CHO-K1 cells are transiently transfected with plasmids containing

the HERG potassium channel, KCR1 polypeptide, and MiRP1 (pg 96, lines 9-15) and that voltage clamp protocols are used to measure potassium currents (pg 96, lines 18-34; pg 97, lines 1-5). However, the specification does not teach that any potassium channels are to be utilized in the assay other than the HERG potassium channel as set forth in SEQ ID NO: 3. The description in the specification that all possible potassium channels could be utilized in the assay is not adequate written description of an entire genus of potassium channels. The skilled artisan cannot envision the potassium channels of the encompassed methods, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The state of the art also discloses that over 13 subfamilies of potassium channel have been described, including voltage-gated channels and voltage-insensitive channels (Lehmann-Horn et al., pg 1329-1332). Lehmann-Horn et al. discuss mutations (including point mutations) in *potassium* channels that cause a wide spectrum of hereditary and somatic conditions and diseases.

(ii) Applicant argues that contrary to the Patent Office's assertions, the line of cases cited (*Fiers v. Revel, Amgen v. Chugai*, and *Fiddes v. Baird*) are inapplicable to the current rejection, and that the holdings in these cases involved issues and facts that are not clearly applicable to the claimed method. It is noted that Applicant summarizes these cases. Additionally, Applicant asserts that these cases are inapplicable to the current invention because their holdings are based upon the unpredictability of the art of cloning genes and cDNAs. Applicant indicates the

claimed method is one that can be applied to any potassium channel polypeptide and that the method does not change irrespective of the potassium channel polypeptide.

Applicant's arguments have been fully considered but are not found to be persuasive. The cases cited by the Examiner in the previous Office Action of 10 November 2003 are applicable to the written description rejection in the instant application. *Fiers v. Revel, Amgen v. Chugai*, and *Fiddes v. Baird* are not in conflict with binding precedent. The skilled artisan cannot envision all possible potassium channels of the encompassed methods, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. One cannot describe what one has not conceived. Adequate written description requires more than a mere statement that it is part of the invention. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

(iii) Applicant asserts that the written description requirement does not require an applicant to disclose that which is known to those of skill in the art. Applicant submits that the written description requirement does not demand the disclosure of the sequences of all potassium channel polypeptides that were known as of the date of filing of the instant application.

Applicant states that at a minimum, Applicant is in possession of every potassium channel the sequence for which was publicly available as of the filing date of the instant application. Applicant contends that the Patent Office is overstating the holding of *Vas-Cath Inc. v. Mahurkar*. Applicant asserts that the Patent Office has not undertaken a case-by-case analysis and that the Patent Office's mere reference to the cases (*Fiers v. Revel, Amgen v. Chugai, and Fiddes v. Baird*) cannot simply be extrapolated to a finding of lack of written description of the pending claims.

Applicant's arguments have been fully considered but are not found to be persuasive. Again, as discussed above, the cases cited by the Examiner in the previous Office Action of 10 November 2003 are applicable to the written description rejection in the instant application. The description in the specification that all possible potassium channels could be utilized in the claimed assay is not adequate written description of an entire genus of potassium channels. The claimed method required the use of the potassium channels, and thus the specification is required to provide adequate written description of those channels. The skilled artisan cannot envision the potassium channels of the encompassed methods, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
27 October 2004

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600